



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2270]

The Drug Supply Chain Security Act Implementation: Product Tracing Requirements for Dispensers--Compliance Policy; Guidance for Industry, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "DSCSA Implementation: Product Tracing Requirements for Dispensers--Compliance Policy." This guidance announces FDA's intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving product tracing information, prior to or at the time of a transaction or do not capture and maintain the product tracing information, as required by the FD&C Act.

DATES: Effective July 1, 2015. For information about enforcement dates, please see the SUPPLEMENTARY INFORMATION section.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA-2015-D-2270, and should be directed to the office listed in the FOR FURTHER INFORMATION CONTACT section.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “DSCSA Implementation: Product Tracing Requirements for Dispensers--Compliance Policy.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). We made this determination because this guidance document provides information pertaining to statutory requirements that take effect on July 1, 2015, regarding the provisions to provide and capture product tracing information under section 582(d)(1) of the FD&C Act (21 U.S.C 360eee-1(d)(1)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency’s good guidance practices (21 CFR 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Pub. L. 113-54) was signed into law. Section 202 of DSCSA adds sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to exchange product tracing information when engaging in transactions involving certain prescription drugs. For dispensers, requirements for the tracing of products through the

pharmaceutical distribution supply chain under section 582(d)(1) of the FD&C Act go into effect on July 1, 2015.

Some dispensers have expressed concern that electronic systems used to exchange, capture, and maintain product tracing information will not be operational by this effective date. Although the DSCSA allows product tracing information to be exchanged through paper in certain circumstances, FDA understands that many dispensers intend to utilize electronic systems to capture and maintain product tracing information. Thus, FDA recognizes that some dispensers may need additional time beyond July 1, 2015, to work with trading partners to ensure that the product tracing information required by section 582 is captured and maintained by dispensers. In light of these concerns, FDA does not intend to take action against dispensers who, prior to November 1, 2015: (1) Accept ownership of product without receiving product tracing information, prior to or at the time of a transaction, as required by section 582(d)(1)(A)(i) of the FD&C Act or (2) do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act. This compliance policy does not extend to other requirements of the FD&C Act applicable to dispensers and other trading partners, including those in section 582, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners. The guidance document explains the scope of the compliance policy in further detail.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: June 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-16401 Filed: 7/2/2015 08:45 am; Publication Date: 7/6/2015]